

SUMMARY OF SAFETY AND EFFECTIVENESS

Product Description

The Horizon Medical Products LifePort® VTX Access System consist of a round port body made of polysulfone, and a silicone or polyurethane catheter. A radiopaque catheter is attached to the outlet stem of the port and secured with a catheter lock by the manufacturer or at implantation by the physician.

The LifePort® VTX Access System is packaged with port and catheter and may be packaged with introducer components. The kit contains basic components required for percutaneous and cut down placement. These components are similar to those currently distributed with other Horizon port products. All kit components are either pre-amendment devices, or have received a determination of substantial equivalence via the pre-market notification process. The intended use of each component remains unchanged. The system is sterilized by EtO with a 10^{-6} Sterility Assurance Level and is labeled as a sterile (single patient use only) device. The LifePort® VTX Access System is packaged with and without introducer components.

Indication for Use

The LifePort® VTX Access System is indicated for any patient requiring repeated access of the vascular system or other selected body site, for delivery of medications, nutritional supplementation, fluids, blood, blood products, and sampling of blood.

Contraindications

The LifePort® VTX Access System should not be implanted in the presence of known or suspected infections, bacteremia, septicemia, and peritonitis, in patients who have exhibited prior intolerance to the materials of construction, or patients whose body size or tissue is insufficient to accommodate the size of the port or catheter.

Horizon Medical Products, Inc. "Special 510(K): Device Modification"
510(k)s Affected: Strato Plastic Port LPS 7513 (K905850); LPS 7013 (K905852); LifePort® Vascular Access System LPS7015 (K911355); LPS7515 (K942848); HMP Polysulfone Port Vascular Access System (K933986) and Vortex® Access System (K010189). Modified Device Name: LifePort® VTX Access System
March 13, 2001

Substantial Equivalence

The LifePort® VTX Access System is substantially equivalent to the following devices:

1. Strato Plastic Port LPS 7513
510(k) #: K905852
SE Date: 4/19/91
2. Strato Plastic Port LPS 7013
510(k) #: K905850
SE Date: 4/19/91
3. Strato Plastic Port LPS 7515
510(k) #: K911355
SE Date: 02/01/95
4. LifePort® Vascular Access System LPS7015
510(k) #: K942848
SE Date: 4/15/91
5. HMP Polysulfone Port Vascular Access System (Triumph-1®)
510(k) #: K933986
SE Date: 02/25/94
6. Vortex® Access System
510(k) #: K010189
SE Date: 02/12/01

Certification, Summary, and Bibliography for the Vortex® Access System

Horizon Medical Products hereby certifies that a reasonable search has been conducted of scientific information known or otherwise available to it regarding implantable intravascular infusion technology. To the best of our knowledge, set out below as part of the 510(k) submission is a summary of and citation to all adverse safety and effectiveness data regarding implantable intravascular ports, including the LifePort® VTX Access System. The summary and bibliography are derived from published scientific literature and from unpublished laboratory, preclinical, and clinical data from other implantable vascular access systems. It should be noted that the data below does not reflect the rate of incidence of the

Horizon Medical Products, Inc. "Special 510(K); Device Modification"

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March 13, 2001

complications and therefore is not an accurate representation of complication rates of vascular access ports.

Types and Potential Reported Problems

Reported Patient Events

- Surgical complications; Risks normally associated with local or general anesthesia, surgery and post-operative recovery.
- Intolerance reaction to implanted device.
- Vascular thrombosis; asymptomatic partial thrombosis.
- Erosion/perforation of the port through the skin.
- Infection: exit site, catheter tunnel, port pocket.
- Systemic infection or sepsis; bacteremia.
- Obstruction/occlusion: thrombosis, precipitation, malposition.
- Dislodgment due to Twiddler's syndrome.
- Skin erosion, cracking, irritation, necrosis; edema/erythema; minor skin breakdown at the site of needle insertion; hematosis.
- Extravasation causing local inflammatory reaction with or without which may lead to tenderness, pain, and/or paresthesia; burning or stinging at the infusion site.
- Phlebitis
- Embolus
- Brachial nerve plexus
- Difficulty accessing port
- Thrombophlebitis
- Bleeding
- Local cellulitis around the exit site of the catheter
- Persistent withdrawal occlusion; may be related to thrombotic occlusion of the catheter tip.
- Tendon or nerve damage.
- Cardiac decompensation.
- Respiratory distress.
- Pain during infusion; pain in the access extremity.
- Cardiac arrhythmias
- Right atrial puncture.
- Vein puncture.
- Hemothorax
- Cardiac tamponade.

Horizon Medical Products, Inc. "Special 510(K): Device Modification"

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Reported device events

- Extravasation/infiltration from port due to: needle dislodgment, catheter tip dislodgment/displacement, inadequate needle stabilization, inadequate location of the portal body, catheter damage.
- Catheter kinking/knotting.
- Catheter embolus.
- Insertion malposition.
- Thrombosis of catheter.
- Embolism of catheter.
- Device occlusion.
- Catheter disconnection between portal and catheter.
- Catheter migration.
- Port leakage.
- Septal rupture.
- Fragmentation of the silicone septum.
- Poor catheter placement.
- Fibrin sheath formation on the catheter and/or catheter tip.
- Device movement, rotation, or extrusion.
- Catheter malposition, shear, fracture, occlusion, dislodgment, leakage or rupture.
- Resistance to infusion due to catheter not patent; difficulty drawing blood.
- Needle puncture to catheter.

REFERENCES FOR IMPLANTABLE VASCULAR ACCESS PORTS

1. Barbara Stevens, R.N., OCN, CCRA; Sue Ellen Barton, R.N., OCN; Marjorie Brechbill, R.N., OCN; Sue Moenter, R.N. OCN; Anna Lou Piel, R.N; Darcel Shankle, R.N., OCN. Conventional Vascular Ports vs. The Vortex "Clear-Flow" Reservoir Port, JVAD, Volume 3 No.3, Summer 2000, Page:1-4
2. Camp-Sorrell, D. Implantable ports-Everything You Always Wanted to Know. Journal of Intravenous Nursing September/October, 1992; 15(5) Page: 262-273
3. Denise Macklin, BSN, RNC CRNI Turbulent Flow and Catheter Residue, JVAN Volume 3 No. 3, Page 14
4. Dido Franceschi, M.D., Mary Ann Specht, R.N. and Charles Farrell, M.D., Implantable Venous Access Device, Journal of Cardiovascular Surgery, Volume 30 1989, Page: 124-129
6. Joetta Deswarte, R.N. Experience with Residue in the Reservoirs of Implanted Ports, JVAN Volume 3, Number 3, Summer 1993, Page: 16-18
7. Suzanne F. Herbst, RN, MA Nurse Consultant, NAVAN Founder, "Accumulation of Blood Products and Drug Precipitates in VADs: A Set Up for Trouble; JVAN Volume 3 No. 3 Summer 93; Page: 9-12
8. Phyllis Dearborn, Judith s. De Muth, Abby B. requarth, and Sandra E. Ward "Nurse and Patient Satisfaction with Three Types of Venous Access Devices" ONF- Volume 24, No 1 Supplement , 1997 Page:34 - 39
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10. Nancy Moureau, BSN, CRNI Focus on Prevention of Vascular Access Device Complications, JVAD, Summer 1999, Page 1-4
11. Nancy Moureau, BSN, CRNI Practicing prevention with Implanted Ports, JVAD, Fall 1999, Page 30-35
12. Shetty PC, Mody MK, Kastan DJ, Sharma RP, Burke MW, Venugopal C, Burke TH; Outcome of 350 Implanted Chest Ports Placed By Interventional Radiologists; J Vasc. Interv. Radiol; 1997 Nov-Dec.8 (6): 991-5r Trouble, JVAN Volume 3 No.3, Page: 9-13
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14. Walker-Andrews S.C., Andrews J.C., Knutsen C. et al. A new Subcutaneous Infusion Port for simplified Long-term Venous Access. In: Ensminger, M.D., Selam, J.L., eds. Updates in drug delivery systems. Mt Kisco, NY: Futura, 1989; 45-52

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Penny M. Northcutt
Director of Regulatory Affairs
Horizon Medical Products, Incorporated
1 Horizon Way
Manchester, Georgia 31816

Re: K010767

Trade Name: Lifeport® VTX Access System, Model VTX
7000 Series

Regulatory Class: II

Product Code: LJT

Dated: March 23, 2001

Received: March 26, 2001

Dear Ms. Northcutt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

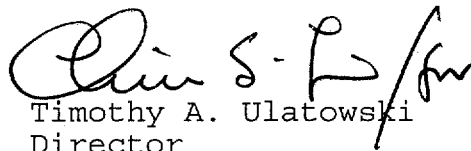
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Timothy A. Ulatowski
Director

Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



PREMARKET NOTIFICATION
INDICATION FOR USE STATEMENT

510(k) Number: K010 767

Device Name: LifePort® VTX Access System

Indication for Use:

The LifePort® VTX Access System is indicated for any patient requiring repeated access of the vascular system, for delivery of medications, nutritional supplementation, fluids, blood, blood products, and sampling of blood.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ or Over-the-Counter Use ☐

Rafaela Ciccardi
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010767

Revised Indication For Use Statement

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